

Bill no.:	Committee Print 4
Amendment no.:	15
Date offered:	6/21/02
Disposition:	Ruled as Non-Germane

COMMITTEE PRINT
OFFERED BY MR. BROWN OF OHIO

At the end of the bill, add the following:

**TITLE X—AFFORDABLE
 PHARMACEUTICALS
 Subtitle A—Greater Access to
 Affordable Pharmaceuticals**

SEC. 1001. PATENT CERTIFICATION.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B), by striking clause (iii) and inserting the following:

“(iii)(I) If the applicant made a certification described in paragraph (2)(A)(vii)(IV) and—

“(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; and

“(bb) the applicant does not bring an action for declaratory judgment authorized in subclause (II) before the expiration of the 60-



June 19, 2002

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1 day period beginning on the date on which the
2 notice provided under paragraph (2)(B)(ii) was
3 received;

4 the approval shall be made effective on the expira-
5 tion of 60 days after the date on which the notice
6 provided under paragraph (2)(B)(ii) was received,
7 provided none of the conditions for denial of ap-
8 proval in paragraph (4) apply.

9 “(II) With respect to an applicant who made a
10 certification described in paragraph (2)(A)(vii)(IV),
11 if an action referred to in item (aa) of subclause (I)
12 is brought before the expiration of the period de-
13 scribed in such item, or if the applicant brings an
14 action for declaratory judgment of invalidity or non-
15 infringement of such patent (which action is hereby
16 authorized) before the expiration of the period de-
17 scribed in item (bb) of such subclause, the approval
18 shall, provided none of the conditions for denial of
19 approval in paragraph (4) apply, be made effective
20 in accordance with the following:

21 “(aa) If the action is an action referred to
22 in subclause (I)(aa), and neither the holder of
23 the approved application nor the owner of the
24 patent seek a preliminary injunction prohibiting
25 the applicant from engaging in the commercial



June 19, 2002

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1 manufacture or sale (or both) of the drug, the
2 approval shall be made effective on the expira-
3 tion of 60 days after the date on which the no-
4 tice provided under paragraph (2)(B)(ii) was
5 received.

6 “(bb) If the action is an action referred to
7 in subclause (I)(aa), and such a preliminary in-
8 junction is sought and the court denies the mo-
9 tion, the approval shall be made effective on the
10 date on which the court denies the injunction.

11 “(cc) If neither item (aa) nor (bb) applies,
12 and the holding of the court in the decision in
13 the action is that the patent is invalid or was
14 not infringed, the approval shall be made effec-
15 tive on the date of the decision of the court.

16 “(dd) If neither item (aa) nor (bb) applies,
17 and the holding of the court in the decision in
18 the action is that the patent was infringed, the
19 approval shall be made effective on such date as
20 the court orders under section 271(e)(4)(A) of
21 title 35, United States Code.”; and

22 (2) by redesignating subparagraphs (C) and
23 (D) as subparagraphs (D) and (E), respectively, and
24 inserting after subparagraph (B) the following sub-
25 paragraph:



1 “(C) With respect to a civil action described in sub-
2 paragraph (B)(iii)(II):

3 “(i) Each of the parties shall reasonably cooper-
4 ate in expediting the action.

5 “(ii) If the notice under paragraph (2)(B)(ii)
6 contains an address for the receipt of expedited noti-
7 fication of such an action, the plaintiff shall, on the
8 date the complaint is filed in the court, simulta-
9 neously cause a notification of such action to be de-
10 livered to such address by the next business day.

11 “(iii) An action for a declaratory judgment au-
12 thorized in such subparagraph may not be brought
13 by the applicant until the expiration of 45 days after
14 the date the notice provided under paragraph
15 (2)(B)(ii) was received, except that if information on
16 the patent involved has been published under sub-
17 section (c)(2) for at least one year after the date on
18 which the application under this subsection was filed
19 in relation to the listed drug involved, the applicant
20 may immediately bring such an action for declara-
21 tory judgment.

22 “(iv) Any such action shall be brought in the
23 judicial district in which the defendant has its prin-
24 cipal place of business or a regular and established
25 place of business.”.



1 (b) NEW DRUG APPLICATIONS.—Section 505(c)(3)
2 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(c)(3)) is amended by striking subparagraph (C) and
4 inserting the following:

5 “(C)(i)(I) If the applicant made a certification
6 described in subsection (b)(2)(A)(iv) and—

7 “(aa) no action is brought for infringement
8 of a patent that is the subject of the certifi-
9 cation before the expiration of the 45-day pe-
10 riod beginning on the date on which the notice
11 provided under subsection (b)(3)(B) was re-
12 ceived; and

13 “(bb) the applicant does not bring an ac-
14 tion for declaratory judgment authorized in
15 subclause (II) before the expiration of the 60-
16 day period beginning on the date on which the
17 notice provided under subsection (b)(3)(B) was
18 received;

19 the approval shall be made effective on the expira-
20 tion of 60 days after the date on which the notice
21 provided under subsection (b)(3)(B) was received,
22 provided that none of the conditions for refusal of
23 approval in subsection (d) apply.

24 “(II) With respect to an applicant who made a
25 certification described in subsection (b)(2)(A)(iv), if



1 an action referred to in item (aa) of subclause (I)
2 is brought before the expiration of the period de-
3 scribed in such item, or if the applicant brings an
4 action for declaratory judgment of invalidity or non-
5 infringement of such patent (which action is hereby
6 authorized) before the expiration of the period de-
7 scribed in item (bb) of such subclause, the approval
8 shall, provided none of the conditions for refusal of
9 approval in subsection (d) apply, be made effective
10 in accordance with the following:

11 “(aa) If the action is an action referred to
12 in subclause (I)(aa), and neither the holder of
13 the approved application nor the owner of the
14 patent seek a preliminary injunction prohibiting
15 the applicant from engaging in the commercial
16 manufacture or sale (or both) of the drug, the
17 approval shall be made effective on the expira-
18 tion of 60 days after the date on which the no-
19 tice provided under subsection (b)(3)(B) was re-
20 ceived.

21 “(bb) If the action is an action referred to
22 in subclause (I)(aa), and such a preliminary in-
23 junction is sought and the court denies the mo-
24 tion, the approval shall be made effective on the
25 date on which the court denies the injunction.



June 19, 2002

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1 “(cc) If neither item (aa) nor (bb) applies,
2 and the holding of the court in the decision in
3 the action is that the patent is invalid or was
4 not infringed, the approval shall be made effective
5 on the date of the decision of the court.

6 “(dd) If neither item (aa) nor (bb) applies,
7 and the holding of the court in the decision in
8 the action is that the patent was infringed, the
9 approval shall be made effective on such date as
10 the court orders under section 271(e)(4)(A) of
11 title 35, United States Code.

12 “(ii) With respect to a civil action described in
13 clause (i)(II):

14 “(I) Each of the parties shall reasonably
15 cooperate in expediting the action.

16 “(II) If the notice under subsection
17 (b)(3)(B) contains an address for the receipt of
18 expedited notification of such an action, the
19 plaintiff shall, on the date the complaint is filed
20 in the court, simultaneously cause a notification
21 of such action to be delivered to such address
22 by the next business day.

23 “(III) An action for a declaratory judgment
24 authorized in such clause may not be
25 brought by the applicant until the expiration of



1 45 days after the date the notice provided
2 under subsection (b)(3)(B) was received, except
3 that if information on the patent involved has
4 been published under paragraph (2) for at least
5 one year after the date on which the application
6 was filed in relation to the drug involved, the
7 applicant may immediately bring such an action
8 for declaratory judgment.

9 “(IV) Any such action shall be brought in
10 the judicial district in which the defendant has
11 its principal place of business or a regular and
12 established place of business.”.

13 (c) EFFECTIVE DATE.—The amendments made by
14 this section shall not apply to an application submitted
15 under section 505(b)(1) or 505(j) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355) before June 7,
17 2002.

18 **Subtitle B—Notification of Agree-**
19 **ments Affecting the Sale or Mar-**
20 **keting of Generic Drugs**

21 **SEC. 1011. DEFINITIONS.**

22 In this subtitle:

23 (1) AGREEMENT.—The term “agreement”
24 means an agreement under section 1 of the Sherman



1 Act (15 U.S.C. 1) or section 5 of the Federal Trade
2 Commission Act (15 U.S.C. 45).

3 (2) ANTITRUST LAWS.—The term “antitrust
4 laws” has the same meaning as in section 1 of the
5 Clayton Act (15 U.S.C. 12), except that such term
6 includes section 5 of the Federal Trade Commission
7 Act (15 U.S.C. 45) to the extent that such section
8 applies to unfair methods of competition.

9 (3) ANDA.—The term “ANDA” means an Ab-
10 breviated New Drug Application, as defined under
11 section 505(j) of the Federal Food, Drug and Cos-
12 metic Act.

13 (4) BRAND NAME DRUG COMPANY.—The term
14 “brand name drug company” means a person en-
15 gaged in the manufacture or marketing of a drug
16 approved under section 505(b) of the Federal Food,
17 Drug and Cosmetic Act.

18 (5) COMMISSION.—The term “Commission”
19 means the Federal Trade Commission.

20 (6) FDA.—The term “FDA” means the United
21 States Food and Drug Administration.

22 (7) GENERIC DRUG.—The term “generic drug”
23 means a product that is the subject of an ANDA.

24 (8) GENERIC DRUG APPLICANT.—The term
25 “generic drug applicant” means a person who has

1 filed or received approval for an ANDA under sec-
2 tion 505(j) of the Federal Food, Drug and Cosmetic
3 Act.

4 (9) SECRETARY.—The term “Secretary” means
5 the Secretary of Health and Human Services.

6 **SEC. 1012. NOTIFICATION OF AGREEMENTS AFFECTING**
7 **THE SALE OR MARKETING OF GENERIC**
8 **DRUGS.**

9 A brand name drug company and a generic drug ap-
10 plicant that enter into an agreement regarding the sale
11 or manufacture of a generic drug that the Secretary has
12 determined is the therapeutic equivalent of a brand name
13 drug that is manufactured or marketed by that brand
14 name drug company, or for which the generic drug appli-
15 cant seeks such a determination of therapeutic equiva-
16 lence, and which agreement could have the effect of lim-
17 iting the research, development, manufacture, marketing,
18 or selling of a generic drug that has been or could be ap-
19 proved for sale by the FDA pursuant to an ANDA, shall
20 file with the Commission and the Secretary the text of
21 the agreement, an explanation of the purpose and scope
22 of the agreement, and an explanation of whether the
23 agreement could delay, restrain, limit, or in any way inter-
24 fere with the production, manufacture, or sale of the ge-
25 neric version of the drug in question.



June 19, 2002

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1 **SEC. 1013. FILING DEADLINES.**

2 Any notice, agreement, or other material required to
3 be filed under section 1012 shall be filed with the Commis-
4 sion and the Secretary not later than 10 business days
5 after the date the agreement is executed.

6 **SEC. 1014. ENFORCEMENT.**

7 (a) **CIVIL FINE.**—Any person, or any officer, direc-
8 tor, or partner thereof, who fails to comply with any provi-
9 sion of this subtitle shall be liable for a civil penalty of
10 not more than \$20,000 for each day during which such
11 person is in violation of this subtitle. Such penalty may
12 be recovered in a civil action brought by the United States,
13 or brought by the Commission in accordance with the pro-
14 cedures established in section 16(a)(1) of the Federal
15 Trade Commission Act (15 U.S.C. 56(a)).

16 (b) **COMPLIANCE AND EQUITABLE RELIEF.**—If any
17 person, or any officer, director, partner, agent, or em-
18 ployee thereof, fails to comply with the notification re-
19 quirement under section 1012 of this subtitle, the United
20 States district court may order compliance, and may grant
21 such other equitable relief as the court in its discretion
22 determines necessary or appropriate, upon application of
23 the Commission or the Assistant Attorney General.

24 **SEC. 1015. RULEMAKING.**

25 The Commission, in consultation with the Secretary,
26 and with the concurrence of the Assistant Attorney Gen-

1 eral and by rule in accordance with section 553 of title
2 5, United States Code, consistent with the purposes of this
3 subtitle—

4 (1) may require that the notice described in sec-
5 tion 1012 of this subtitle be in such form and con-
6 tain such documentary material and information rel-
7 evant to the agreement as is necessary and appro-
8 priate to enable the Commission and the Assistant
9 Attorney General to determine whether such agree-
10 ment may violate the antitrust laws;

11 (2) may define the terms used in this subtitle;

12 (3) may exempt classes of persons or agree-
13 ments from the requirements of this subtitle; and

14 (4) may prescribe such other rules as may be
15 necessary and appropriate to carry out the purposes
16 of this subtitle.

17 **SEC. 1016. EFFECTIVE DATES.**

18 this subtitle shall take effect 90 days after the date
19 of enactment of this Act.



June 19, 2002

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